UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WILLIAM KADER, Individually and On Behalf of All Other Persons Similarly Situated,	*	
Plaintiff,	*	
v.	*	Civil Action No. 1:14-cv-14318-ADB
SAREPTA THERAPEUTICS, INC., CHRISTOPHER GARABEDIAN, and SANDESH MAHATME,	*	
Defendants.	*	

MEMORANDUM AND ORDER

This is a securities fraud putative class action. Plaintiff William Kader, and Lead Plaintiffs Morad Ghodooshim, Roger Lam, and Laxmikant Chudasama (collectively, "Plaintiffs") seek to represent a class of all purchasers of securities issued by Sarepta Therapeutics, Inc. ("Sarepta" or "the Company") during a six-month period between April 21, 2014 and October 27, 2014 (the "Class Period"). The named defendants are Sarepta, along with its former CEO, Christopher Garabedian ("Garabedian"), the Company's CFO, Sandesh Mahatme ("Mahatme"), and Edward Kaye, M.D. ("Kaye"), the Company's Chief Medical Officer.[1]

Presently before the Court are (1) Defendants' Motion to Dismiss for failure to state a claim [ECF No. 21], and (2) Plaintiffs' Motion to Strike certain exhibits submitted in support of Defendants' Motion to Dismiss [ECF No. 26]. For the reasons set forth in this Memorandum and

[1]Although Kaye does not appear in the caption of the Amended Complaint, he is named in other sections of the Amended Complaint, and all parties have treated him as a defendant.

Order, Plaintiffs' Motion to Strike is ALLOWED IN PART and DENIED IN PART, and Defendants' Motion to Dismiss is ALLOWED.

I. BACKGROUND

Sarepta is a biopharmaceutical company focused on developing RNA-based therapeutics for the treatment of rare and infectious diseases. In recent years, the company has been developing drug candidates to treat a disease known as Duchenne muscular dystrophy ("DMD"). Sarepta's lead drug candidate is a drug called "eteplirsen." Plaintiffs contend that during the Class Period, Sarepta and its executives made materially misleading statements and omissions regarding the company's ongoing efforts to file a New Drug Application ("NDA") for eteplirsen with the U.S. Food and Drug Administration ("FDA"). Specifically, Plaintiffs allege that the Defendants misstated guidance and omitted information that the FDA purportedly provided to the Company, which pertained to the sufficiency of Sarepta's clinical data on eteplirsen.

Plaintiffs filed their two-count Amended Complaint on March 20, 2015 [ECF No. 17], alleging that by making misrepresentations and material omissions in connection with the purchase or sale of Sarepta's securities, all Defendants violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 (Count I), and the individual Defendants violated Section 20(a) of the Exchange Act (Count II).

On May 11, 2015, Defendants moved to dismiss [ECF No. 21], arguing that the Amended Complaint does not state an actionable claim for securities fraud because (1) Plaintiffs fail to allege any actionable misstatements, and (2) Plaintiffs fail to allege sufficient facts on the element of scienter. In support of their Motion, Defendants filed a Memorandum of Law [ECF No. 22], and a supporting Declaration attaching 27 separate exhibits [ECF No. 23]. Plaintiffs filed an Opposition to the motion to dismiss [ECF No. 25], as well as a Motion to Strike certain

exhibits submitted by Defendants [ECF No. 26]. The parties subsequently filed reply briefs. [ECF Nos. 29, 34]. The Court held a hearing on Defendants' Motion to Dismiss on March 29, 2016.

II. FACTS ALLEGED IN THE AMENDED COMPLAINT

Plaintiffs' Amended Complaint [ECF No. 17] (hereinafter "Compl.") alleges the following facts, which the Court accepts as true for purposes of Defendants' Motion to Dismiss.

A. Sarepta develops eteplirsen for treatment of DMD.

DMD is a rare neuromuscular disorder that causes progressive muscle loss in young boys, leading to severe disability and premature death. The disease is the result of a genetic mutation that causes the dystrophin gene to make inadequate amounts of dystrophin, a protein that plays a key structural role in muscle fiber function and is needed to keep muscles intact. DMD occurs in about one in every 3,500 boys worldwide. See Compl. ¶¶ 4, 33-34. The disease is universally fatal, and the average life expectancy of someone with DMD is only 27 years. Id. ¶¶ 34-35. Currently, there are no approved disease-modifying therapies to treat DMD. Id. ¶ 35.

Sarepta, a biopharmaceutical company, is currently developing drug candidates to treat DMD, including its leading candidate, eteplirsen. Sarepta's main competitor in the field is Prosena Therapeutics, Inc. ("Prosena"), who was also developing a drug candidate to treat DMD. During the Class Period, Prosena, like Sarepta, was undertaking clinical trials and actively pursuing regulatory approval in the United States and Europe. Id. ¶ 37. Plaintiffs allege that Sarepta and Prosena were competing to win first regulatory approval for their respective DMD drugs, and thereby claim a "first-mover advantage" in the DMD drug market. Id. ¶ 38.

B. FDA's New Drug Application Process

Under the Federal Food, Drug, and Cosmetic Act, all "new drugs" must be approved by the FDA before they may be marketed in the United States. See 21 U.S.C. § 355(a). The FDA approves new drugs through the "New Drug Application" process, in which the sponsor of the drug must demonstrate that it has carried out studies sufficient to show that the drug is safe and effective for its intended use. Compl. ¶¶ 42-44. First, sponsors must produce results of preclinical testing in laboratory animals, and thereafter present an Investigational New Drug application ("IND"). The IND outlines, among other things, the sponsor's proposal for future clinical trials in humans. Id. ¶ 44. Human clinical trials can begin only after an IND is approved by the FDA and a local Institutional Review Board ("IRB"). Id. ¶ 45.

Human clinical trials are typically conducted in three phases. Phase I studies are usually conducted in healthy volunteers and focus on the safety of the drug. If Phase I studies do not indicate unacceptable toxicity, the drug moves on to Phase II studies, which obtain preliminary data on whether the drug is effective in treating people for a certain disease or condition. If the Phase II studies suggest evidence of efficacy, the drug moves into Phase III studies, which are intended to gather more information on safety and efficacy by studying the drug across a larger number of participants. Id. ¶ 46.

When a sponsor believes it has conducted sufficient clinical trials, and that those trials demonstrate substantial evidence of efficacy and safety, the sponsor may prepare and submit an NDA, seeking the FDA's approval to market the drug for the treatment of a specific condition or indication. Id. ¶ 49. After an NDA is submitted, the FDA has 60 days to decide whether to accept it for filing and proceed with a review. Id. ¶ 52; see 21 C.F.R. § 314.101(a)(1). If the FDA concludes that the application is "sufficiently complete to permit a substantive review," the NDA

will be accepted, and the FDA will proceed to review the application. 21 C.F.R. § 314.101(a)(1); see also Compl. ¶ 52.

An FDA review team of medical doctors, scientists, and other experts evaluates whether the sponsor's studies show that the drug is safe and effective for its proposed use. Compl. ¶ 58. In addition, the acceptance of an NDA triggers certain deadlines under the Prescription Drug User Fee Act, which requires the FDA to make a determination within 10 months, or within 6 months for certain "priority drugs." Id. ¶ 52. By the end of the review period, the FDA will either approve the NDA or issue a Complete Response Letter. Id. ¶ 61.

The FDA has various programs that allow for the drug approval process to be expedited, to ensure that therapies for serious conditions are available as soon as possible. Id. ¶ 62. One such program is "Fast Track" designation. Id. ¶ 64. Fast Track designation may be granted on the basis of preclinical data, and the sponsor of a drug that receives Fast Track status will typically have more frequent interactions with the FDA during drug development. Id. The FDA granted eteplirsen Fast Track designation in 2007. See Sarepta Therapeutics, Inc. FY2013 10-K [ECF No. 23-1] ("FY2013 10-K"), p. 8. [2]

Drugs with certain Fast Track designations can also obtain a "rolling review" of an NDA application, such that certain segments of the NDA can be submitted piecemeal, instead of in one single submission. Compl. ¶¶ 53-55, 64. Plaintiffs' Complaint alleges that in this case, the FDA "expressed a willingness" to conduct a rolling review of Sarepta's NDA for eteplirsen. Id. ¶ 102. The FDA, however, considers an NDA to be "complete" only when the last segment of the NDA is submitted to the FDA for review. Id. ¶¶ 55, 102.

[2] All page numbers referenced in this Memorandum and Opinion refer to page numbers assigned by the Court's ECF filing system.

Additionally, drug sponsors may seek Accelerated Approval ("AA"), which can also reduce the length of time necessary to complete clinical studies. Id. ¶ 65. AA allows approval of a drug that demonstrates an effect on a "surrogate endpoint" that is reasonably likely to predict clinical benefit, or on a "clinical endpoint" that can be measured earlier than an effect on irreversible morbidity or mortality, and that is reasonably likely to predict an effect on those endpoints, or to produce some other clinical benefit. Id.

C. Eteplirsen Clinical Trials

In 2011, after completing Phase I and II studies for eteplirsen overseas, Sarepta initiated a Phase IIb clinical trial in the United States to measure eteplirsen's ability to meet both a "primary efficacy" surrogate endpoint (*i.e.*, increased production of dystrophin) and a clinical endpoint (*i.e.*, a patient's retained capacity to walk despite the passage of time, referred to as the "6-minute walk test"). See FY2013 10-K, pp. 8-9.

The first phase of the Phase IIb clinical trial, which was referred to as "Study 201," studied the effects of eteplirsen "administered intravenously in two different doses over 24 weeks for the treatment of ambulant boys with DMD." Id. p. 8. Study 201 included 12 participants, all of whom underwent muscle biopsies both prior to starting treatment, and again after 24 weeks of treatment with either eteplirsen or a placebo. Id. The comparative biopsies were designed to determine the amount of dystrophin in the patient's muscle tissue, and whether the amount of dystrophin had changed over time. See Compl. ¶ 82. Dystrophin protein can be visualized by staining the muscle sample with a special dye. Id. Plaintiffs allege that this method, which requires an expert to view and analyze slides of muscle tissue, is "inherently subjective." Id.

After Sarepta reported encouraging results from Study 201, the participants were then enrolled in an extension study ("Study 202"), in which all participants would receive varying doses of eteplirsen for an additional 24 weeks. See FY2013 10-K, p. 9. At week 48, a third biopsy would be obtained for analysis. See id. For Study 202, the "primary efficacy endpoint" was a change in dystrophin-positive muscle fibers in the biopsy tissue from baseline to week 48. Id. The "primary clinical outcome measure" was the change in a patient's performance in the "six minute walk test" from baseline to week 48. Id. Study 202 was subsequently extended to include a "long term extension phase," in which patients would continue to be followed for safety and clinical outcomes approximately every 12 weeks. Id.

During the Class Period, all of Sarepta's muscle biopsy dystrophin analyses were conducted at a single location, at Nationwide Children's Hospital in Columbus, Ohio, and the clinical review was overseen by one medical doctor. Compl. ¶ 83. Plaintiffs allege that throughout the Class Period, the FDA was in possession of all of Sarepta's dystrophin data. Id. ¶ 84.

D. Events during the Class Period

On April 21, 2014, at the beginning of the Class Period, Sarepta issued a press release announcing that by the end of 2014, it planned to submit an NDA to the FDA for the approval of eteplirsen as a treatment for DMD. Compl. ¶ 6. According to the Company, the timing of its NDA submission was "based on a guidance letter from the FDA that proposed a strategy regarding the submission of its NDA for eteplirsen under a potential Accelerated Approval pathway." Id.; see also Sarepta Therapeutics, Inc. Form 8-K, dated April 21, 2014 [ECF No. 23-7] ("4/21/2014 8-K"), p. 6. In its press release, the Company quoted from portions of the FDA's guidance letter, noting that the FDA had "stated that 'with additional data to support the efficacy

and safety of eteplirsen for the treatment of DMD, an NDA should be fileable,'" and that the FDA had "outlined examples of additional data and analysis that, if positive, will be important to enhance the acceptability of an NDA filing by addressing areas of ongoing concern in the dataset." 4/21/2014 8-K, p. 6; see also Compl. ¶ 92. Sarepta's press release, however, also disclosed that the FDA had "expressed concerns about methodological problems in the assessments of dystrophin and, 'remain[s] skeptical about the persuasiveness of the (dystrophin) data.'" 4/21/2014 8-K, p. 8 (quoting FDA guidance letter) (alteration added). Sarepta noted that, as a result, the FDA WAS "'uncertain whether the existing dystrophin biomarker data will be persuasive enough to serve as a surrogate endpoint . . . .'" Id.

On the same day, the Company held a conference call with analysts and investors to discuss Sarepta's announcement. See Sarepta Conference Call Transcript dated April 21, 2014 [ECF No. 23-8] ("4/21/2014 Conference Call"), p. 4. On the call, Defendant Garabedian, Sarepta's CEO, explained that between November 2013 and April 2014, Sarepta had attended four meetings with the FDA, and that the FDA's newest guidance letter served as the "final meeting minutes" for those interactions. See id., p. 4. Garabedian stated that the FDA's letter provided "clear direction" to "help move our DMD program forward," and that Sarepta "now understand[s] how the FDA suggests that we enhance our existing data set over the short term, to increase their confidence in our data, and increase the likelihood of an acceptable NDA filing, and a potentially favorable review for an accelerated approval of eteplirsen." Id.

Garabedian explained that the FDA's guidance letter set forth two alternative pathways to achieve accelerated approval of eteplirsen. See id., p. 5. The first approach, as described by Garabedian, "would be to grant eteplirsen an accelerated approval on the clinical data from our Study 201/202 study, based on the 6-minute walk test results, as an intermediate clinical

endpoint." Id. "The second approach," he continued, "would be to grant eteplirsen an accelerated approval on the dystrophin biomarker as a surrogate endpoint . . . ." Id. Garabedian went on to note that "[w]ith respect to [using] dystrophin as a surrogate endpoint to support accelerated approval, the FDA indicated that it will collaborate with Sarepta to conduct a detailed review of the current dystrophin biomarker data from our Phase II study. If the results of the review were deemed adequate, it may support accelerated approval." Id. "To this end, over the coming months, the FDA will be meeting with the pathologist that supervised the dystrophin quantification, to better understand the blinded review, the detailed methodologies, and the controlled conditions in which the various dystrophin measures were conducted." Id., pp. 5-6.

During the call, Garabedian also stated that "[w]hile we continue to believe that our current dataset is strong enough on its own to be considered for an NDA filing, we believe the additional data that we will collect over the next six to eight months, if positive, will provide the FDA with supporting evidence of eteplirsen's safety and efficacy, that should result in an acceptable NDA for filing." Id., p. 4; see also Compl. ¶ 7.

Later in the call, Defendant Kaye reiterated that the Company "still believe[d]" that its existing dataset was "strong enough to support an NDA filing and is worthy of a review for a potential accelerated approval," and that the Company "could submit a NDA now." Compl. ¶¶ 7, 96; see also 4/21/2014 Conference Call, p. 12.[3]

After Sarepta's announcement, shares of Sarepta increased 39.26%, to close at $33.98 per share on April 21, 2014, on unusually heavy trading volume. Compl. ¶ 8. The next day, Sarepta disclosed that it planned to offer up to $100 million of its common stock in an underwritten

[3] Although the Complaint attributes these statements to Kaye, the transcript of the Conference Call indicates that it was Garabedian who spoke. For purposes of Defendants' Motion to Dismiss, however, the Court will accept Plaintiffs' allegation regarding Kaye at face value.

public offering. Id. ¶ 9. On April 29, 2014, Sarepta sold 2,650,000 shares of common stock in a public offering, at a price of $38.00 per share, resulting in net proceeds to the Company of approximately $94.5 million. Id. ¶ 10.

In May 2014, the FDA visited National Children's Hospital in Columbus and reviewed Sarepta's clinical trial site and protocols. Id. ¶ 86. Plaintiffs allege that two months later, in July 2014, Sarepta received a "request for a reassessment" from the FDA, which asked that Sarepta's primary dystrophin data be reassessed by "independent pathologists at independent labs." Id. ¶ 13. Defendants did not disclose this specific information to the public during the Class Period. Id.

On October 27, 2014, Sarepta issued another press release announcing that the Company had received a "regulatory update" from the FDA regarding its planned NDA submission for eteplirsen. Id. ¶ 14; see also Sarepta Therapeutics, Inc. Form 8-K dated October 27, 2014 [ECF No. 23-6] ("10/27/2014 8-K"), p. 3. Specifically, Sarepta stated that the FDA "provided updated guidance regarding the specific data to be included as part of, or at the time of, Sarepta's NDA submission." 10/27/2014 8-K, p. 6. The updated guidance, as reported by Sarepta, "states that additional data are now required as part of the NDA submission including the results from an independent assessment of dystrophin images and the 168-week clinical data from study 202." Id. It also "requests more specific data including a minimum duration of safety in new patients exposed to eteplirsen, patient-level natural history data to be obtained by Sarepta from independent academic institutions, and MRI data from a recent study conducted by an independent academic group." Id. Sarepta's press release went on to note that, based on the FDA's "updated guidance," Sarepta would not submit an NDA until mid-year 2015. 10/27/2014 8-K, p. 6; see also Compl. ¶¶ 14, 88.

Also on October 27, 2014, Sarepta executives participated in a conference call, during which Defendant Kaye confirmed that one of the concerns raised by the FDA was that all of Sarepta's dystrophin testing had taken place at a single site. He noted that this concern would be addressed, at least in part, by having more than one pathologist review the dystrophin slides that would be produced by a forthcoming, fourth biopsy. See Compl. ¶ 14; see also Sarepta Conference Call Transcript dated October 27, 2014 [ECF No. 23-22] ("10/27/2014 Conf. Call"), p. 7.

After the Company's October 27, 2014 announcement, shares of Sarepta declined $7.65 per share, or more than 32%, to close at $15.91 per share on October 27, 2014, on unusually heavy trading volume. Compl. ¶ 15.

Three days later, on October 30, 2014 the FDA issued a public "Duchenne Muscular Dystrophy Statement," in which it addressed "questions the agency has received from DMD patients, their families, and others in the community who are concerned about the timing of the filing of an NDA for eteplirsen." Id. ¶ 133. Because Plaintiffs rely heavily on the FDA's October 30, 2014 Statement to support their allegations that Defendants' prior representations were false and misleading, the Court sets out the FDA's Statement in its entirety:

> FDA recognizes the unmet medical need in Duchenne muscular dystrophy (DMD), the devastating nature of the disease for patients and their families, and the urgency to make new treatments available. We remain committed to working with all companies to expedite the development and approval of safe and effective drugs to treat this disease.
>
> On October 27, 2014, Sarepta Therapeutics released a statement and had a conference call regarding guidance received from FDA in a September 2014 meeting regarding its planned New Drug Application (NDA) for eteplirsen, to treat patients with DMD. To the extent allowed by laws restricting release of confidential information about experimental drugs, FDA is addressing questions the agency has received from DMD patients, their families, and others in the community who are concerned about the timing of the filing of an NDA for eteplirsen.

Over the past several years, FDA has worked extensively with Sarepta on the development of eteplirsen, and provided guidance with respect to the data that would be necessary to determine whether it is effective and support filing of an NDA. Following a meeting with FDA last April, Sarepta announced on April 21, 2014, that "with additional data to support the efficacy and safety of eteplirsen for the treatment of DMD, an NDA should be fileable." Sarepta also announced at that time that FDA had communicated that there were areas of concern in the existing database, and that FDA had provided Sarepta with "examples of additional data and analyses that, if positive, would be important to enhance the acceptability of an NDA filing…." Sarepta announced at the time its plans to submit an NDA for eteplirsen by the end of 2014.

Since the April 2014 meeting, FDA has been working intensively to help Sarepta provide the additional data and analyses needed to support an NDA. FDA understands the considerable disappointment in the Duchenne community following Sarepta's October 27 announcement that the previous time frame for submitting the NDA for eteplirsen cannot be met.

In its advice to Sarepta, FDA has consistently stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of the muscle protein dystrophin. (Eteplirsen's proposed mechanism of action is through increasing production of this muscle protein.) As described by Sarepta in its October 27 statement, the need for additional data and analyses to support the NDA was reinforced by an FDA inspection of the clinical site where dystrophin analyses had been conducted. It is important to note that the agency did not find any evidence of fraud at this site, as has been perceived by some. FDA is concerned that the methods used to measure dystrophin were not adequately robust to support an NDA submission. Thus, FDA provided Sarepta with detailed recommendations on how to improve these dystrophin analyses, and FDA's most recent advice was consistent with the advice provided after the April 2014 meeting.

FDA has also been consistent in its guidance to Sarepta that it would be necessary to submit data from the ongoing open-label trial of eteplirsen (Study 202) in an NDA, along with data from natural history studies that could show that patients treated with eteplirsen experienced slower decline in physical function. FDA has worked closely with Sarepta in efforts to obtain these natural history data from investigators.

FDA has consistently advised Sarepta that data from additional patients, beyond the patients included in Study 202, would be critical to our assessment of the safety and efficacy of eteplirsen. In our April 2014 letter to Sarepta, FDA strongly encouraged Sarepta to begin enrollment of new patients as soon as possible.

FDA has expressed willingness to conduct a "rolling review" of Sarepta's NDA. Under a rolling review, companies can submit, and FDA can review, portions of an application as they are completed. Once submission of all components is complete,

> the review clock begins. FDA expects the NDA for eteplirsen will qualify for a priority review.
>
> FDA also plans to present the NDA for eteplirsen to a public advisory committee meeting before making a decision on approval. This will afford FDA the ability to gain advice from outside experts and interested stakeholders on the adequacy of the data to support approval, including the possibility of "accelerated approval" – a mechanism to approve drugs in particular situations prior to the availability of definitive evidence of effectiveness.
>
> FDA understands the dire urgency of the situation and the importance of our actions to the DMD community. FDA will continue to work with Sarepta in their efforts to provide the data it considers critical to FDA's ability to review the NDA and reach a decision on approvability.

Compl. ¶ 133.

E. Alleged Misrepresentations

Plaintiffs' Complaint alleges that during the Class Period, Defendants made a number of false and misleading statements and omissions regarding the sufficiency of Sarepta's existing dystrophin data.[4] Plaintiffs contend that "[t]hroughout the Class Period, Defendants were aware that the FDA had requested additional data to support the efficacy and safety of eteplirsen for an NDA to be fileable." Compl. ¶ 118. Despite this alleged knowledge, Defendants "falsely"

[4] The Complaint also alleged a second category of misstatements, namely, representations that the FDA would be willing to accept additional clinical data from Sarepta *after* the Company submitted its NDA. Plaintiffs' theory was based on the assumption that a drug sponsor must obtain advance written permission from the FDA to submit material, required portions of its NDA after the initial submission. See Compl. ¶ 101. Plaintiffs asserted that because the FDA never gave Sarepta written permission to make any late submissions, Defendants' representations that the FDA had expressed a willingness to accept supplemental data after Sarepta's NDA filing were false and misleading. See Compl. ¶ 102. In their Motion to Dismiss, Defendants argued that this theory was based upon the false premise that advance permission was required, and that Plaintiffs' claims should therefore be dismissed to the extent they relied on this theory. Plaintiffs, in their Opposition, did not spill much ink addressing Defendants' argument on this front. At the March 29, 2016 hearing before the Court, Plaintiffs' counsel acknowledged that Plaintiffs do not intend to pursue securities fraud claims based on this theory. Accordingly, the Court need not recite the Complaint's allegations on this point, and Defendants' Motion to Dismiss is ALLOWED with regard to the alleged misstatements set forth in ¶¶ 101-117 of Plaintiffs' Amended Complaint.

claimed that the Company's existing dystrophin data was sufficient to file a NDA. Id. Plaintiffs further allege that the falsity of these statements was revealed when the FDA issued its Duchenne Muscular Dystrophy Statement on October 30, 2014, in which it explained that in its advice to Sarepta, the FDA "has consistently stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of the muscle protein dystrophin," and that "[a]s described by Sarepta in its October 27 statement, the need for additional data and analyses to support the NDA was reinforced by an FDA inspection of the clinical site where dystrophin analyses had been conducted." Id. The FDA also noted that after the clinical site inspection, the FDA "provided Sarepta with detailed recommendations on how to improve these dystrophin analyses," and that the FDA's "most recent advice was consistent with the advice provided after the April 2014 meeting." Id.

Plaintiffs point to four specific statements made during the Class Period that they claim were false and misleading. First, during the April 21, 2014 conference call with Sarepta's investors and analysts, Garabedian stated that:

> [t]he way to think about it is almost like a sliding scale. We could submit our NDA now on the existing data set, but the FDA has highlighted questions and concerns, and they are not as comfortable with just the existing data set. We hear them, and while we could submit an NDA now, we believe that we are going to be in a much better position if we just wait for some of these additional pieces of data.

Compl. ¶ 119; see also 4/21/2014 Conference Call p. 12.

Second, during a May 7, 2014 Deutsche Bank Healthcare Conference, Garabedian made similar statements, indicating that the FDA had provided guidance that an NDA:

> should be fileable with additional safety and efficacy, but when they describe all the different ways that we could supplement that additional safety and efficacy, and I would also add perspectives on the current data set, they really looked – they gave us almost a sliding scale of saying there are many ways that you can bolster the

> current data set. I'm paraphrasing here, but they didn't say we're not telling you can't submit an NDA tomorrow on the existing data set. We're not saying it wouldn't be fileable on the current data set. But we're telling you that we've raised enough concerns on the existing data set that you would bolster your case for an NDA filing and potentially a favorable review if you allow us to do a more detailed review of your dystrophin methodology, if you maybe consider getting a fourth biopsy, if you add exposure data from the new patients that are enrolled in the confirmatory study, if you supplement it with the 144-week data.

Transcript of Sarepta Therapeutics, Inc. at Deutsche Bank Healthcare Conference dated May 7, 2014 [ECF No. 23-9] ("5/7/2014 Deutsche Bank Healthcare Conference") p. 3; see also Compl. ¶ 122.

Third, during the May 13, 2014 Bank of America Health Care Conference, Garabedian stated that the FDA, in its communications with Sarepta, had indicated that:

> the existing dystrophin data set could be sufficient on its own to qualify for accelerated approval, particularly after a collaboration with the company to go through a detailed review of exactly what was done to generate that data set. So that means they have the data, they have all of the methodologies that we've used to conduct the analysis, but they've not yet gone and actually talked to the pediatric neurologist in charge of the histopathology lab. They've not talked to the reviewers, they've not talked to the technicians, they did not completely understand how did we control for this analysis? What conditions was ensuring the quality of this analysis? How was the blinded review handled? We are very confident in the site we selected and the entire staff who led the dystrophin analysis. I believe they're world-class, and we think once the FDA meets this team and understands exactly how it was done, they will have the same confidence we have in our existing dystrophin data set.

Transcript of Sarepta Therapeutics, Inc. at Bank of America Merrill Lynch Healthcare Conference dated May 13, 2014 [ECF No. 23-11] ("5/13/2014 BofA Healthcare Conference") p. 4; see also Compl. ¶ 125.

Finally, during Sarepta's August 7, 2014 Earnings Conference Call with investors and analysts, Garabedian noted that:

> we continue to have productive dialogue with the FDA regarding our dystrophin methodology. As a reminder, the FDA indicated in its April guidance that if, after further detailed review, they were to find the currently available dystrophin biomarker data to be adequate, our existing dystrophin data set would have the potential to support accelerated approval. The agency recently completed a site visit with Nationwide Children's Hospital in Columbus, Ohio and met with the leadership and staff of the histopathology lab that conducted our dystrophin analysis and quantification and we continue to work with the FDA to provide greater assurance of the quality and reliability of our dystrophin data in anticipation of a potential NDA filing decision and potential NDA review next year.

Q2 2014 Sarepta Therapeutics Inc. Earnings Call dated August 7, 2014 [ECF No. 23-27] ("8/7/2014 Conference Call") p. 6; see also Compl. ¶ 128.

Plaintiffs allege that each of these statements was materially false or misleading when made, or omitted to state facts necessary to make the statements not misleading, because the FDA had already informed Sarepta that its existing dystrophin data was insufficient, and that the methods used to measure dystrophin were not adequately robust to support an NDA submission. See Compl. ¶ 129. Further, Plaintiffs allege that Garabedian's August 7, 2014 statements were materially misleading for an additional reason: namely, in July 2014, Defendants had received a request from the FDA for reassessment of Sarepta's primary dystrophin endpoint data by independent pathologists at independent labs. Id.

F. Scienter

Plaintiffs further allege that Defendants made these allegedly false and misleading statements with scienter, and they point to several allegations from which they claim scienter may be inferred. First, Plaintiffs allege that the individual Defendants, including Garabedian, "actively communicated with the FDA and were present during the Company's interactions with the FDA." Compl. ¶ 105(a). Thus, to the extent that Defendants' representations to the public misstated the guidance provided by the FDA, Plaintiffs contend that Defendants' firsthand

knowledge of the actual guidance supports an inference of scienter. Second, Plaintiffs note that although Sarepta has released numerous statements paraphrasing the FDA's purported April 2014 guidance, the Company has not made the full text of the FDA's "guidance letter" publicly available. Id. ¶ 105(d). Because these communications are potentially exculpatory, Plaintiffs argue that Defendants' failure to release them "supports a strong inference of scienter." Id.

With respect to the allegedly false and misleading statements made during Sarepta's April 21, 2014 conference call with investors and analysts, Plaintiffs say scienter may be inferred because the Defendants' alleged misstatements "led to an immediate and drastic increase in the price of the Company's shares, which the Company capitalized on by announcing a public offering of its stock the next day." Compl. ¶¶ 105(c), 121(c). Thus, Plaintiffs allege that the timing of the April 21st statements, relative to the Company's initial public offering, also supports an inference of scienter.

Finally, with respect to the allegedly false and misleading statements made during Sarepta's August 7, 2014 conference call with investors and analysts, Plaintiffs allege that scienter may be inferred from the fact that Sarepta had received the FDA's request for reassessment of its dystrophin data no later than July 2014. See Compl. ¶ 130. Thus, Defendants had "specific knowledge, or were reckless in not knowing, that Sarepta's dystrophin data were insufficient to file an NDA." Id. ¶ 130(a).

III. PLAINTIFFS' MOTION TO STRIKE

The Court first addresses Plaintiffs' Motion to Strike ten exhibits[5] attached to the Declaration of Mark D. Vaughn [ECF No. 23] ("Vaughn Decl.") which Defendants submitted in

[5] Specifically, Plaintiffs move to strike Exhibits 2, 3, 4, 16, 17, 18, 19, 21, 23, and 24 to the Vaughn Declaration.

support of their Motion to Dismiss the Amended Complaint. Plaintiffs also move to strike Exhibit A to Defendants' Memorandum of Law in Support of their Motion to Dismiss [ECF No. 22], which is a reference chart cataloguing the purported pleading deficiencies in Plaintiffs' Amended Complaint.

The Court DENIES Plaintiffs' Motion to Strike the chart in Exhibit A to Defendants' Memorandum of Law. Although the better course would have been for Defendants to seek leave to file excess pages in advance of the filing, the Court would have allowed a motion to that effect. Further, the chart does not introduce any new arguments, and the Court finds Defendants' efforts to synthesize the information presented in their moving papers to be useful.

Plaintiffs' Motion to Strike exhibits to the Vaughn Declaration is ALLOWED with respect to Exhibits 2, 3, 16, 17, 18, 19, 21, and 23, but DENIED with respect to Exhibits 4 and 24. As Defendants note, most of the disputed exhibits merely provide background information regarding Sarepta's ongoing efforts to develop a DMD drug candidate. Although these exhibits may have provided helpful context, they are not properly before the Court, nor are they essential to evaluating the sufficiency of the Complaint. Therefore, the Court will allow the motion to strike Exhibits 2, 3, 16, 17, 18, 19, 21, and 23 and has not considered these exhibits in ruling upon Defendants' Motion to Dismiss.

Defendants, however, argue that Exhibits 4 and 24 to the Vaughn Declaration provide more than mere context and relate directly to Plaintiffs' theory of the case.

Exhibit 4 is a copy of the FDA's official response to a citizen petition urging the FDA to "Say YES to Accelerated Approval for safe, effective therapies for children with Duchenne [muscular dystrophy]." See Vaughn Decl. ¶ 6. The FDA's response, which is signed by Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research, appears to have been

published on the official White House website on July 29, 2014. See Vaughn Decl. Ex. 4, [ECF No. 23-4] ("Woodcock Statement").[6] In her statement, Woodcock acknowledges the petitioners' concerns about the lack of FDA-approved therapies to treat DMD and states that the FDA "share[s] your sense of urgency to make safe and effective drugs available for patients with Duchenne muscular dystrophy as soon as possible." Id. The statement goes on to note that the FDA is "actively engaged with a number of drug companies focused on developing new drugs for [DMD], including Sarepta . . . ." Id. Woodcock also states that the FDA is conducting "ongoing analyses of eteplirsen and other drugs for the treatment of [DMD]," and that while those assessments are "rigorous and extensive," the FDA "recognize[s] the urgency of the needs of patients with [DMD]." Id. The Woodcock Statement further notes that Sarepta "has publicly announced its intention to file a New Drug Application for eteplirsen by the end of 2014 as well as plans to initiate several additional clinical studies with eteplirsen later this year[.]" Id. The Statement assures petitioners that the FDA is "willing to explore the use of all potential pathways for the approval of drugs for [DMD] (including accelerated approval) as appropriate." Id.

Plaintiffs do not dispute the authenticity of the Woodcock Statement. Rather, they move to strike it on relevance grounds, arguing that "it is unclear how a response to an anonymous petition bears relevance to the allegations in the Complaint." [ECF No. 27 p. 15]. Defendants, however, insist that the Woodcock Statement is not only relevant, but *central* to Plaintiffs' claims, as it represents the FDA's "lone public statement" during the Class Period that addresses the prospective timing of Sarepta's NDA filing for eteplirsen.

[6] As of the date of this Memorandum and Order, the FDA's July 29, 2014 Response is still available on the White House website. See https://petitions.whitehouse.gov/response/drug-approval-pathways-and-duchenne-muscular-dystrophy, *last visited* March 31, 2016.

The Court agrees with Defendants and denies the motion to strike Exhibit 4. "Ordinarily . . . any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden, unless the proceeding is properly converted into one for summary judgment under Rule 56." Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). The First Circuit recognizes "narrow exceptions" to this rule for "documents the authenticity of which are not disputed by the parties; for official public records; for documents central to the plaintiffs' claim; or for documents sufficiently referred to in the complaint." Id.

Where, as here, Plaintiffs do not dispute the authenticity of the Woodcock Statement, it is appropriate for the Court to consider this document on Defendants' Motion to Dismiss. See id. The Court also finds that the Woodcock Statement, insofar as it is an official statement of the FDA, and published on a government website, constitutes a "public record" of which the Court may take judicial notice. See Gent v. CUNA Mut. Ins. Soc'y, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (taking judicial notice of relevant facts provided on CDC website, which were "not subject to reasonable dispute") (citing Fed. R. Evid. 201); Rock v. Lifeline Sys. Co., No. CIV.A. 13-11833-MBB, 2014 WL 1652613, at *12 (D. Mass. Apr. 22, 2014) (court may take judicial notice and consider documents posted on a government website); Denius v. Dunlap, 330 F.3d 919, 926-27 (7th Cir. 2003) (holding that court abused its discretion in withdrawing its judicial notice of information posted on official government website).

Furthermore, although the July 29, 2014 Woodcock Statement is not referenced in the Complaint, Plaintiffs do rely on the FDA's subsequent October 30, 2014 Statement regarding eteplirsen and Sarepta. Specifically, Plaintiffs argue that the FDA's October 2014 Statement "refuted" Sarepta's earlier representations to the investing public, "further demonstrating the falsity of Defendants' disclosures during the Class Period." [ECF No. 25 p. 12]. Because the

FDA's October 30, 2014 statement is central to Plaintiffs' allegations, the Court believes that other public comments from the FDA during the Class Period should also be considered on a motion to dismiss. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007) (directing courts to consider, on motions to dismiss securities fraud claims, "the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice"). Although the Court is not considering the FDA's statements for the truth of the matter asserted, the mere existence of such statements may be relevant to the allegedly misleading nature of Defendants' representations and omissions; whether Defendants acted with the requisite scienter; and the total mix of information available to the market during the Class Period. See In re Nuvelo, Inc. Sec. Litig., 668 F. Supp. 2d 1217, 1220 (N.D. Cal. 2009). For all of these reasons, the Court denies Plaintiffs' Motion to Strike Exhibit 4 to the Vaughn Declaration and will consider Exhibit 4 for purposes of Defendants' Motion to Dismiss.

Plaintiffs also move to strike Exhibit 24, which is a "Notice of Recent Developments" filed by different plaintiffs in a separate securities fraud action against Sarepta and the individual Defendants. See Vaughn Decl. Ex. 24 [ECF No. 23-24]. That action is also pending in this District. See Corban v. Sarepta Therapeutics, Inc., et al., No. 1:14-cv-10201-IT (D. Mass.). Although it is "well-accepted that federal courts may take judicial notice of proceedings in other courts if those proceedings have relevance to the matters at hand," Kowalski v. Gagne, 914 F.2d 299, 305 (1st Cir. 1990), it is not clear how the Notice attached at Exhibit 24, or the Corban case more generally, are relevant to determining whether Plaintiffs' Complaint in this action states a viable claim. Notably, the securities fraud claims in Corban involve a different class period, and

are based on different alleged misstatements and omissions than those at issue here. See generally Corban v. Sarepta Therapeutics, Inc., No. 14-CV-10201-IT, 2015 WL 1505693, at *1 - *3 (D. Mass. Mar. 31, 2015). Accordingly, although the Court declines to strike Exhibit 24 to the Vaughn Declaration, it has not relied upon this exhibit for purposes of Defendants' Motion to Dismiss.

Finally, the Court notes that Plaintiffs have not moved to strike Exhibits 1, 5-15, 20, 22, or 25-27 to the Vaughn Declaration, which include copies of the various press releases, public filings, and transcripts containing the alleged misstatements referred to in the Complaint. Accordingly, the Court has considered these exhibits for purposes of Defendants' Motion to Dismiss – not for the truth of the matters asserted therein – but to determine the full content of Defendants' statements, and the context in which Defendants made them. See Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996) (court may "properly consider the relevant entirety of a document integral to or explicitly relied upon in the complaint . . . without converting the motion into one for summary judgment").

IV. DEFENDANTS' MOTION TO DISMISS

A. Legal Standard

"Section 10(b) of the Securities Exchange Act of 1934 forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (quoting 15 U.S.C. § 78j(b)) (alterations and omission in original). In turn, SEC Rule 10b–5 implements § 10(b) by declaring it unlawful, "in connection with the purchase or sale of any security,"

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b–5.

Thus, "[t]o state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015) (internal quotations and citation omitted).[7]

As with any motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must accept all "well-pleaded factual allegations in the Complaint as true and view all reasonable inferences in the plaintiffs' favor." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). To survive a motion to dismiss, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

[7] "Claims brought under section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a), are derivative of 10b – 5 claims." Hill v. Gozani, 638 F.3d 40, 53 (1st Cir. 2011). Section 20(a) provides that once a company has been found to have violated the Act's substantive provisions, "[e]very person who, directly or indirectly, controls" the company "shall also be liable jointly and severally with and to the same extent as [the company] . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a). Here, Plaintiffs allege Section 20(a) claims against the individual Defendants on the grounds that they had "direct and supervisory involvement in the day-to-day operations of the Company," and are therefore "presumed to have had the power to control or influence the particular transactions giving rise to the securities violations" alleged in the Complaint. See Compl. ¶ 180. Accordingly, in order to plead a viable Section 20(a) claim against the individual Defendants, Plaintiffs must first plead an actionable claim under Section 10(b) of the Exchange Act and Rule 10b-5.

Further, because this case involves claims of securities fraud, Plaintiffs must additionally satisfy the Fed. R. Civ. P. 9(b) standard for alleging fraud with particularity, and comply with the heightened pleading requirements imposed by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737. See Advest, Inc., 512 F.3d at 58. The PSLRA "requires plaintiffs' complaint to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (quoting 15 U.S.C. § 78u–4(b)(1)) (alteration in original). If plaintiffs' allegation regarding the statement or omission "'is made on information and belief, the complaint must state with particularity all facts on which that belief is formed.'" Id. (quoting 15 U.S.C. § 78u–4(b)(1)).

The PSLRA also imposes a "rigorous pleading standard" for allegations of scienter, which is a "'mental state embracing intent to deceive, manipulate, or defraud.'" Id. (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n. 12 (1976)). To survive a motion to dismiss, a complaint must state "with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" Abiomed, Inc., 778 F.3d at 240 (quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)). The facts alleged must make the inference of scienter "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc., 551 U.S. at 314. "When there are equally strong inferences for and against scienter, the draw is awarded to the plaintiff." Waters Corp., 632 F.3d at 757.

B. Analysis

Defendants argue that the Amended Complaint fails to state an actionable claim for securities fraud for two primary reasons: (1) Plaintiffs fail to plead any facts plausibly suggesting

that Defendants' statements or omissions were materially false or misleading; and (2) Plaintiffs do not allege facts sufficient to support a "strong inference" that Defendants acted with scienter.[8]

1. Misleading nature of statements or omissions

First, Plaintiffs' Complaint broadly alleges that throughout the Class Period, Defendants' expressions of confidence in Sarepta's existing dystrophin data set were materially false and misleading – or omitted to state material facts necessary to make them not misleading – because "the FDA had informed [Sarepta] that its existing dystrophin data was insufficient and that the methods used to measure dystrophin were not adequately robust to support an NDA submission." Compl. ¶ 120. Similarly, Plaintiffs allege that "[t]hroughout the Class Period, Defendants were aware that the FDA had requested additional data to support the efficacy and safety of eteplirsen for an NDA to be fileable." Compl. ¶ 118.

"The plaintiff's factual allegations are ordinarily assumed to be true in passing on the adequacy of the complaint, which need not plead evidence." Penalbert-Rosa v. Fortuno-Burset, 631 F.3d 592, 595 (1st Cir. 2011). "But 'ordinarily' does not mean 'always': some allegations, while not stating ultimate legal conclusions, are nevertheless so threadbare or speculative that they fail to cross 'the line between the conclusory and the factual.'" Id. (quoting Twombly, 550 U.S. at 557 n. 5). For example, this is the case where the "bareness of the factual allegations makes clear that the plaintiff is merely speculating about the fact alleged and therefore has not

[8] Defendants also argue that many of the alleged misstatements are non-actionable statements of opinion, and/or forward-looking statements protected by the PSLRA's safe-harbor provisions. Because the Court concludes that Plaintiffs have not adequately alleged that the statements omissions were false or misleading, or that Defendants acted with the requisite scienter, it need not reach this argument.

shown that it is plausible that the allegation is true." Rodriguez-Vives v. P.R. Firefighters Corps., 743 F.3d 278, 286 (1st Cir. 2014).

Here, the Complaint contains no facts directly supporting Plaintiffs' contention that at the start of the Class Period in April 2014, the FDA had already informed Sarepta that its existing dystrophin data was insufficient to support an NDA. Instead, Plaintiffs suggest that this inference can reasonably be drawn from the timing, diction, and tone of the FDA's October 30, 2014 Statement to the DMD community, which followed Sarepta's announcement that its NDA filing would be delayed. Specifically, Plaintiffs point to the FDA's October 30, 2014 statement that "[i]n its advice to Sarepta, FDA has *consistently* stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of . . . dystrophin," and that "the need for additional data and analyses to support the NDA was *reinforced* by an FDA inspection of the clinical site where dystrophin analyses had been conducted." (emphasis added). The FDA also stated that following this site visit, it had "provided Sarepta with detailed recommendations on how to improve these dystrophin analyses, and FDA's most recent advice was *consistent with* advice provided after the April 2014 meeting." (emphasis added). Plaintiffs insist that the use of words like "consistent" and "reinforce" plausibly suggest that the FDA had previously told Sarepta that its dystrophin data was insufficient to support an NDA, and that the FDA issued its October 30, 2014 Statement to correct Sarepta's suggestion that the NDA filing was being delayed due to "updated" FDA guidance.

Even when viewing the facts in the light most favorable to Plaintiffs, the Court finds that the FDA's October 30, 2014 Statement cannot support the weight of that inference. First, the FDA indicated that its Statement was intended to address "questions the agency has received from DMD patients, their families, and others in the community who are concerned about the

timing of the filing of an NDA for eteplirsen." This suggests that the FDA spoke primarily to address questions from the DMD community, and not for the purpose of correcting any prior statements made by Sarepta. Furthermore, the FDA's Statement contains commentary that tends to confirm, rather than correct, Sarepta's representations to the market. The FDA stated, with no apparent disagreement, that "[f]ollowing a meeting with FDA last April, Sarepta announced on April 21, 2014 that 'with additional data to support the efficacy and safety of eteplirsen . . . an NDA should be fileable." The FDA also noted that Sarepta had disclosed the fact that the Agency "had communicated that there were areas of concern in the existing database, and that FDA had provided Sarepta with 'examples of additional data and analyses that, if positive, would be important to *enhance the acceptability* of an NDA filing.'" (emphasis added). The FDA also noted that Sarepta had announced "its plans to submit an NDA for eteplirsen by the end of 2014," but the Agency did not seemingly take issue with either of these statements. These considerations detract from the plausibility of Plaintiffs' theory.

In addition, the FDA affirmatively stated that it was "important to note" that it "did not find any evidence of fraud" at Sarepta's clinical trial site, "as has been perceived by some." The FDA went on to note that it "is" (in the present tense) "concerned that the methods used to measure dystrophin were not adequately robust to support an NDA submission." To that point, the FDA said it had recently provided Sarepta with recommendations on how to improve its dystrophin analyses, and that this most recent advice was "consistent with" advice provided after the April 2014 meeting. Critically, however, the FDA did not state that it had told Sarepta in April 2014 that the Company's existing dystrophin data was inadequate to support an NDA submission. At best, the FDA's Statement plausibly implies that in April 2014, it had raised concerns about the dystrophin data and given Sarepta recommendations on how to strengthen the

data set, thereby "enhancing" the acceptability of an eventual NDA filing. Thus, the FDA's characterization of its own April 2014 guidance is not at all inconsistent with representations made by Defendants during the Class Period. When read as a whole, the FDA's October 30, 2014 Statement does not plausibly imply that it told Sarepta as early as April 2014 that the existing dystrophin data would be insufficient to support an NDA.[9]

Further, even assuming, *arguendo*, that the FDA had informed Sarepta in April 2014 that its existing dystrophin data was not sufficient to support an NDA filing, the Defendants' statements do not actually mislead investors on this point. Although Defendants do make statements to the effect that Sarepta "could submit our NDA now," they immediately clarify that it would be unwise to do so, because the FDA had "highlighted questions and concerns" and indicated that it was "not as comfortable with just the existing data set." 4/21/2014 Conference Call p. 12; see also 5/7/2014 Deutsche Bank Healthcare Conference Call p. 3 (noting that while the FDA was "not saying [an NDA] wouldn't be fileable on the current data set," the FDA was telling Sarepta "that we've raised enough concerns on the existing data set that you would bolster your case for an NDA filing and potentially a favorable review if you allow us to do a more detailed review of your dystrophin methodology . . . ."). When read in context, each of the statements clearly communicates that filing an NDA without further data and analysis – although

[9] The July 29, 2014 Woodcock Statement further detracts from the plausibility of Plaintiffs' theory that the FDA had previously notified Sarepta about some fatal deficiency in its existing dystrophin data. To the contrary, the Woodcock Statement notes that the FDA, in late July 2014, was "actively engaged" with Sarepta and others on their development of DMD drugs, and that the FDA was conducting "ongoing analyses" of eteplirsen which were "rigorous and extensive." [ECF No. 24-3]. Woodcock also noted, without any apparent disagreement, that Sarepta had "publicly announced its intention to file a New Drug Application for eteplirsen by the end of 2014," and assured petitioners that the FDA remained willing to explore accelerated approval pathways to approving a DMD drug. Id.

perhaps possible – would be unadvisable. Thus, Plaintiffs have not plausibly alleged that Defendants' statements were materially misleading to investors.

Plaintiffs, perhaps realizing the weaknesses in their theory, filed an Opposition to Defendants' Motion to Dismiss that seemingly narrows the scope of their claims. Plaintiffs now focus on the FDA's request that Sarepta have independent pathologists at independent labs reassess the dystrophin data, and the impact of that request on Defendants' statements about the "sufficiency" of the existing data. See [ECF No. 25, p. 27] (arguing that Defendants "falsely portrayed the sufficiency of their dystrophin data and omitted that the FDA required independent pathologists at independent labs to assess the dystrophin data as part of the NDA").

Plaintiffs' Complaint alleges that the FDA made this request for reassessment in July 2014. See, e.g., Compl. ¶¶ 13, 87, 129, 130(a), 149. If that allegation is accurate, Defendants' statements on April 21, 2014, May 7, 2014, and May 13, 2014 could not have been false or misleading in the manner alleged by Plaintiffs, because Defendants could not have misrepresented or omitted to disclose what the FDA had not yet told them.[10]

[10] In an attempt to avoid this result, Plaintiffs' counsel requested at oral argument that the Court take judicial notice of a transcript from an August 12, 2015 motion hearing in the Corban case, 14-cv-10201-IT (D. Mass), in which Judge Talwani heard argument on a motion to amend the complaint in that action. During that hearing, Plaintiffs' counsel quoted from what was represented to be pre-meeting comments from the FDA, in which the FDA purportedly asked Sarepta to "confirm with an independent laboratory the immunohistochemical findings for dystrophin and associated proteins in the previously collected tissue block," and suggested that this and other concerns should be "addressed prior to filing." By pointing the Court to the hearing transcript and this alleged document, Plaintiffs are suggesting there is reason to believe that the FDA communicated its "request for reassessment" to Sarepta earlier than July 2014. The Court, however, declines to consider the August 12, 2015 hearing transcript or the purported document discussed at the hearing for purposes of this Motion to Dismiss. Although the Court may take judicial notice of proceedings in other cases, it generally cannot do so for the truth of any matters discussed during those proceedings. See Goguen ex rel. Estate of Goguen v. Textron, Inc., 234 F.R.D. 13, 19 (D. Mass. 2006). Furthermore, even assuming that the FDA's request for reassessment pre-dated July 2014, this fact is not necessarily inconsistent with Defendants'

This leaves the August 7, 2014 earnings conference call with investors and analysts, which post-dates Sarepta's alleged receipt of the FDA's July 2014 "request for reassessment." After examining a transcript of the conference call, the Court concludes that it does not contain affirmative statements that could be deemed false or misleading in light of the facts alleged. First, in contrast to earlier statements during the Class Period, Defendants did not make any statements expressing confidence in the "sufficiency" of Sarepta's existing dystrophin data. Garabedian merely stated that the Company "continue[d] to have productive dialogue with the FDA regarding our dystrophin methodology[,]" and reminded the audience that the FDA indicated in its April 2014 guidance "that if, after further detailed review, they were to find the currently available dystrophin biomarker data to be adequate, our existing dystrophin data set would have the potential to support accelerated approval." 8/7/2014 Conference Call, p. 6. Garabedian also disclosed that the FDA had "recently completed a site visit with Nationwide Children's Hospital in Columbus, Ohio and met with the leadership and staff of the histopathology lab that conducted our dystrophin analysis and quantification . . . ." Id. He noted that Sarepta would "continue to work with the FDA to provide greater assurance of the quality and reliability of our dystrophin data in anticipation of a potential NDA filing decision and potential NDA review next year." Id. Therefore, although Defendants did not disclose the FDA's request for reassessment, they also did not affirmatively state that the existing data was presently sufficient to support an NDA. Instead, they truthfully represented that a review of that data was ongoing.

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expressions of confidence in their existing data set, nor would it necessarily be a material development requiring disclosure, as explained more fully, *infra*.

Furthermore, the fact that Sarepta received a "request for reassessment" of its existing dystrophin data by independent pathologists does not equate to a statement from the FDA that the existing data was categorically inadequate, or even a suggestion that the data was "insufficient" to support an NDA filing. At best, it suggests that the FDA had concerns about the methodology, and that it wanted Sarepta to have independent experts reassess the data and either affirm or reject the reliability of Sarepta's results before the data was submitted in an NDA. Therefore, Defendants' expressions of confidence in the "sufficiency" of the data are not at odds with the FDA's request for reassessment, where the sufficiency of the data set was an open question at that point in time.[11] Thus, to the extent Plaintiffs' claims are premised on affirmative statements regarding the sufficiency of Sarepta's existing data set, the Court finds that Plaintiffs fail to allege facts plausibly suggesting that these statements were false or misleading.

Alternatively, Plaintiffs allege that Defendants made actionable omissions when they failed to disclose during the Class Period that Sarepta had received a request for reassessment of its dystrophin data in July 2014. It is well-established that "Section 10(b) does not create an affirmative duty to disclose." In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 41 (1st Cir. 2014). "A duty to disclose information earlier omitted arises only when affirmative statements were made and the speaker 'fail[ed] to reveal those facts that are needed so that what was revealed would not be so incomplete as to mislead.'" Id. (quoting In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012)) (alteration in original).

[11] It appears that Sarepta eventually filed its NDA for eteplirsen with the FDA in May 2015, see Declaration of Justin G. Florence, Exhibit 1 [ECF No. 30-1] (May 19, 2015 Sarepta Press Release), and the FDA accepted the NDA for filing later that year. See August 25, 2015 Sarepta Press Release, *available at* http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&p=irol-newsArticle&ID=2081965, *last visited* March 31, 2016.

Here, the only instance in which Sarepta "spoke" during the Class Period after July 2014 was the August 7, 2014 earnings conference call with investors. Plaintiffs do not explain in their Complaint or their Opposition how disclosing the FDA's request for reassessment was necessary to make the August 7th conference call not misleading. Although Plaintiffs argue that "failure to disclose FDA's serious criticism" of clinical trial data can be a "material omission," they rely on cases with very different facts. For example, in In re Transkaryotic Therapies, Inc. Securities Litigation, 319 F. Supp. 2d 152 (D. Mass. 2004), the defendant pharmaceutical company failed to disclose FDA criticism of the company's clinical trials, which the FDA had issued in a "Complete Review Letter" in response to the company's new drug application. See id. at 156. The Complete Review Letter concluded, in no uncertain terms, that the studies "failed to demonstrate efficacy," that one of the studies suffered from "serious methodological deficiencies," and that "additional analyses or otherwise revised analyses of the clinical data you have submitted *will be unable to address* this deficiency." Id. (emphasis added). Thus, the FDA recommended that the company "conduct additional clinical studies and submit the results." Id. Not only did the defendants fail to disclose this decisive FDA guidance; they also issued press releases stating that the FDA's Complete Review Letter merely "requested additional data and asked for further explanation in several areas." Id. Not surprisingly, the court in Transkaryotic found that plaintiffs adequately alleged material omissions. Id. at 159-60.

Here, in contrast, Defendants allegedly failed to disclose the FDA's request for an "independent reassessment" of Sarepta's existing dystrophin data. There was no final decision to communicate—merely interim feedback in the context of an ongoing dialogue on Sarepta's planned NDA submission, which had yet to be filed. The interim and indefinite nature of the FDA's reassessment request undermines the notion that Defendants had a duty to disclose it. See,

e.g., Vallabhaneni v. Endocyte, Inc., No. 14-cv-01048, 2016 WL 51260, at *12 -*14 (S.D. Ind. Jan. 4, 2016) (holding that company did not have duty to disclose interim feedback from FDA criticizing its clinical trial methodology, where criticism was not so severe as to suggest that the drug was ineffective, or that further studies would be futile); In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 541-42 (S.D.N.Y. 2015) (allowing defendants' motion to dismiss, and noting that multiple courts have "rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review"), aff'd sub nom. Tongue v. Sanofi, No. 15-588-CV, 2016 WL 851797 (2d Cir. Mar. 4, 2016); Noble Asset Mgmt. v. Allos Therapeutics, Inc., No. CIVA-04CV-1030, 2005 WL 4161977, *7 (D. Colo. Oct. 20, 2005). Although failure to disclose nearly-fatal criticism from the FDA might constitute an actionable omission in an appropriate case, see Transkaryotic, 319 F. Supp. 2d at 159, the FDA's July 2014 reassessment request does rise to that level.

Furthermore, the Court finds it significant that throughout the Class Period, Sarepta expressly and repeatedly informed the investing public about the FDA's concerns with the methodology Sarepta used to assess the dystrophin data. See, e.g., 4/21/2014 8-K, p. 8 (noting that the FDA "expressed concerns about methodological problems in the assessments of dystrophin and, 'remain skeptical about the persuasiveness of the (dystrophin) data,'" such that "the Agency is 'uncertain whether the existing dystrophin biomarker data will be persuasive enough to serve as a surrogate endpoint'"); 4/21/2014 Conference Call ("We could submit our NDA now on the existing data set, but the FDA has highlighted questions and concerns, and they are not as comfortable with just the existing data set."); 5/7/2014 Deutsche Bank Conference Call p. 3 (paraphrasing FDA as saying that "we're telling you that we've raised enough concerns

on the existing data set that you would bolster your case for an NDA filing and potentially a favorable review if you allow us to do a more detailed review of your dystrophin methodology . . . .”). These disclosures undercut Plaintiffs’ suggestion that the FDA’s formal request for reassessment in July 2014 was a watershed event that should have been disclosed, or that Defendants’ failure to do so was materially misleading.

For these reasons, the Court finds that Plaintiffs have not alleged sufficient facts to plausibly suggest that Defendants made affirmatively misleading statements, or that they omitted to disclose information needed to make their statements not misleading.

2. Scienter

For similar reasons, the Court also finds that Plaintiffs do not allege facts giving rise to a “strong inference” of scienter – *i.e.*, one that is “at least as compelling as any opposing inference one could draw from the facts alleged.” Tellabs, Inc., 551 U.S. at 324. To survive dismissal, Plaintiffs would have needed to allege facts strongly suggesting that Defendants were knowingly dishonest or reckless in failing to disclose the FDA’s reassessment request. See Boston Sci. Corp., 686 F.3d at 31. In Boston Scientific, the First Circuit observed that:

> [i]n cases where we have found the pleading standard satisfied, the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so.

Id. Here, Plaintiffs allege no such facts in their Amended Complaint.

Further, the few facts Plaintiffs proffer in support of their scienter theory are legally inadequate. First, the Defendants’ presence at FDA meetings, and their resulting first-hand knowledge of the FDA’s guidance, does not support a strong inference of scienter. As previously noted, Plaintiffs have not offered any compelling explanation of why Defendants’ statements or

omissions were fundamentally at odds with any guidance the FDA purportedly provided. Additionally, any inference that the Defendants knowingly or recklessly failed to disclose the FDA's request for reassessment is undermined by the Company's repeated disclosures about the FDA's concerns with the existing dataset. See In re Genzyme Corp. Sec. Litig., No. CIV. 09-11299-GAO, 2012 WL 1076124, at *12 (D. Mass. Mar. 30, 2012) (finding that defendants' "repeated and timely disclosures of material information seriously undermine an inference of intent to deceive"), aff'd, 754 F.3d 31 (1st Cir. 2014); In re Polaroid Corp. Sec. Litig., 134 F. Supp. 2d 176, 186 (D. Mass. 2001) ("[A]ny indication of scienter that one might draw from Polaroid's arguably overly optimistic statements about future business is offset by the Company's cautionary admissions in its . . . annual reports.").

Plaintiffs also contend that Defendants' failure to release the full text of the FDA's April 2014 "guidance letter" supports a strong inference of scienter. The Court disagrees. Generally, companies are under no obligation to disclose their written communications with the FDA to the general public, and the Court declines to infer scienter from the fact that Defendants have refused to produce the guidance letter to Plaintiffs in this securities fraud action.

Similarly, the Court rejects Plaintiffs' theory that scienter can be inferred from the timing of Sarepta's public offering, which occurred the week after the Company's April 21, 2014 press release. Standing alone, "the existence of a public offering during the period of alleged misrepresentations cannot itself lead to an inference of scienter." In re Boston Sci. Corp. Sec. Litig., No. CIV.A. 10-10593-DPW, 2011 WL 4381889, at *15 (D. Mass. Sept. 19, 2011) aff'd, 686 F.3d 21 (1st Cir. 2012); see also Coyne v. Metabolix, Inc., 943 F. Supp. 2d 259, 271-72 (D. Mass. 2013) (theory that defendants lied in order to inflate stock prices was a "generalized

motive [that] could apply to any corporate executive at any company anywhere in the United States," and therefore did not give rise to a strong inference of scienter).

Finally, at oral argument, counsel for Plaintiffs argued that scienter can be inferred from the fact that Sarepta was engaged in a "desperate" race with its competitor, Prosena, to secure first-mover advantage in the DMD drug market. See Compl. ¶¶ 37-38. Even assuming this allegation to be true, it does not strongly imply that Defendants intentionally or recklessly misled potential investors. Ultimately, it would be the FDA – not the investing public – that would decide whether to approve a drug for marketing and sale. Thus, Plaintiffs have not plausibly alleged a motive to mislead.[12]

After considering all the facts alleged as an integrated whole, N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008), the Court finds that Plaintiffs have not met the PSLRA's pleading standard with respect to scienter. Although Plaintiffs allege facts that could theoretically support a finding of scienter, under these circumstances, "the inference of the requisite intent to defraud is certainly not cogent or compelling." Genzyme Corp., 754 F.3d at 42.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Strike [ECF No. 26] is ALLOWED IN PART and DENIED IN PART. Defendants' Motion to Dismiss the Amended Complaint [ECF No. 21] is ALLOWED, and all claims against the Defendants are hereby DISMISSED.[13]

[12] Although Plaintiffs offered additional arguments for scienter in their Opposition brief (including the departure of some Sarepta executives, including Garabedian), such facts were not alleged in the Complaint, and the Court declines to consider them for purposes of this Motion to Dismiss.

[13] Because Plaintiffs fail to plead a viable claim for securities fraud under Section 10 and Rule 10b-5, all derivative claims against the individual Defendants necessarily fail as well. See Hill v. Gozani, 638 F.3d 40, 70 (1st Cir. 2011).

SO ORDERED.

Dated: April 5, 2016

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE